

**ATTACHMENTS**

- *Ex parte* Bobsein et al., (Appeal No. 2005-1332)
- *In re* Arkley, 172 U.S.P.Q. 524 (CCPA 1972)

**REMARKS**

This Amendment is responsive to the Office Action mailed January 4, 2008. With this Amendment, claims 1-20 and 22-26 are cancelled, claim 21 is amended, and claim 27 is added. Claims 21 and 27 are pending.

Support for the amendment to claim 21 and for new claim 27 can be found throughout the specification and claims as filed, including, e.g., original claims 1, 10, and 22; page 11, lines 12-21; page 12, first paragraph; and page 17, line 6 through page 19, lines 20.

Election/Restriction

Applicants thank the Examiner for reconsideration of the requirement for election/restriction set forth in the paper mailed September 19, 2007. Applicants note that the restriction requirement is made final, holding Group II (claims 9-10, 21-24, and 26) to be under prosecution. Applicants further note that claims 1-20 and 22-26 are hereby cancelled and new claim 27 is added. Applicants submit that claim 27 is examinable along with the elected subject matter. In the event that the Examiner deems claim 27 as directed to a separate and distinct invention, Applicants hereby request rejoinder of claim 27 upon the indication of allowability of claim 21. Applicants reserve the right to file one or more divisional or continuation applications directed to the non-elected subject matter.

Information Disclosure Statement

Applicants thank the Examiner for considering the Information Disclosure Statements filed on January 24, 2006 and April 18, 2006, and for indicating such consideration by including initialed copies of the Form PTO-1449 submitted therewith.

Claim Objections

The Office Action objects to claim 9 for allegedly depending from a withdrawn claim.

In response, Applicants submit that the instant Amendment renders the objection to claim 9 moot. Accordingly, this ground of objection should be withdrawn.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Office Action rejects claim 10 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Office Action alleges that claim 10 is indefinite because the scope of the claim cannot be determined with respect to the section “b”, which recites a DNA hybridizing with the DNA having the nucleotide sequence shown in SEQ ID NO: 2 under stringent conditions.

In response, and without expressing agreement or acquiescence to the rejection of record, Applicants submit that the instant amendment renders the rejection of claim 10 under 35 U.S.C. § 112, second paragraph, moot.

Accordingly, withdrawal of the rejection is requested.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claim 10 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and as allegedly claiming subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Office Action states that disclosure of SEQ ID NO: 2 is not representative of DNA hybridizing with the DNA having the nucleotide sequence shown in SEQ ID NO: 2 under stringent conditions and encoding a protein have immune-stimulating activity, or DNA having a partial sequence of the DNA of SEQ ID NO: 2 and encoding a protein have immune-stimulating activity.

In response, and without expressing agreement or acquiescence to the rejection of record, Applicants submit that the instant amendment renders the rejection of claim 10 under 35 U.S.C. § 112, first paragraph, moot.

Accordingly, withdrawal of the rejection is requested.

Claim Rejections – 35 U.S.C. § 102

The Office Action rejects claims 9, 10, 21-24, and 26 under 35 U.S.C. § 102(b) as allegedly anticipated by WO 99/04265 as evidenced by Accession No. AAX40073. In particular, the Office Action states that WO 99/04265 teaches a nucleotide sequence that encodes the polypeptide having amino acid sequence SEQ ID NO: 1, as evidenced by AAX40073. The Office Action also states that the nucleic acids described in WO 99/04265 may be comprised within pharmaceutical compositions, and that the pharmaceutical compositions may further comprise an adjuvant.

The Office Action also rejects claims 9, 10, 21, 23, 24, and 26 under 35 U.S.C. § 102(b) as allegedly anticipated by Scanlan (U.S. 6,403,373; June 11, 2002; hereinafter SCANLAN).

The Office Action also rejects claims 9, 10, 21, 23, 24, and 26 under 35 U.S.C. § 102(b) as allegedly anticipated by Scanlan-II (Scanlan, M.J. et al., *Int. J. Cancer* **76**:652-658, 1998; hereinafter SCANLAN-II).

The Office Action also rejects claims 9, 10, 21, 23, 24, and 26 under 35 U.S.C. § 102(b) as allegedly anticipated by Nakatsura et al. (*Biochem. Biophys. Res. Comm.* **281**:936-944, 2001; hereinafter NAKATSURA) or Ishihara et al. (*Biochim. Biophys. Acta* **1444**:138-142, 1999; hereinafter ISHIHARA) (U.S. 6,403,373; June 11, 2002).

The Office Action also rejects claims 9, 10, 21, 23, 24, and 26 under 35 U.S.C. § 102(e) as allegedly anticipated by Horne (U.S. 6,974,667; filed June 14, 2001; hereinafter HORNE), Kaser (U.S. 6,727,006; filed June 30, 2001; hereinafter KASER), or Cocks (U.S. 6,607,879; filed February 9, 1998; hereinafter COCKS).

In response, Applicants submit that the disclosed and claimed invention is not anticipated by the cited documents. With regard to WO 99/04265, this document discloses a nucleic acid, expressed by colorectal cancer and normal cells, which the document further describes as “similar to heat shock protein 110 family members” (see page 62, lines 23-26). The nucleic acid falls into an extremely large group of disclosed nucleic acid sequences, referred to in the WO 99/04265 document as “NA Group 1”, which code for “cancer associated antigen precursor[s]”

(see paragraph bridging pages 13-14). The document refers to such molecules only as diagnostic agents or as antigens. SCANLAN teaches only nucleic acids with therapeutic and/or diagnostic uses. SCANLAN-II discloses the identification of nucleic acids from cDNA libraries derived from human tumors. NAKATSURA and ISHIHARA also disclose the identification and characterization of nucleic acids from a human pancreatic adenocarcinoma cell line and from HeLa cells, respectively. HORNE, KASER and COCKS also disclose nucleic acids for use either as probes, or in association with liver cancer, and/or for treatment of, e.g., hyperlipidemia.

In contrast, the presently claimed and disclosed subject matter is drawn to a cancer vaccine which comprises the DNA of any of the following (i) or (ii), or recombinant virus or recombinant bacteria comprising said DNA, and further comprises an adjuvant:

(i) a DNA encoding a cancer antigen comprising a protein of any of the following (A) or (B):

(A) a protein having the amino acid sequence shown in SEQ ID NO: 1; or

(B) a protein having an amino acid sequence comprising a substitution, deletion, insertion, and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and also having immune-stimulating activity;

(ii) a DNA of any one of the following (a), (b), and (c):

(a) DNA having the nucleotide sequence shown in SEQ ID NO: 2;

(b) DNA having 90% or more homology to SEQ ID NO: 2, and encoding a protein having immune-stimulating activity; and

(c) DNA having a partial sequence of the DNA of (a) or (b) above, and encoding a protein having immune-stimulating activity.

The disclosed and claimed subject matter is thus directed at a cancer vaccine that has immune-stimulating, therapeutic and/or cancer preventative characteristics.

Applicants submit that none of the cited documents, including the WO 99/04265 document, teach a cancer vaccine as claimed, nor do the documents teach the *specific combination* of recited elements such that they comprise a cancer vaccine. For example, WO 99/04265 broadly discloses the use of any one of at least 816 sequences, but does not disclose Applicants' recited combination of cancer vaccine components.

Applicants further note that for anticipation to exist, the cited documents must clearly and unequivocally disclose the claimed subject matter without any need for picking, choosing, or combining various disclosures. In other words, for anticipation to exist, one must not be required to pick and choose from the disclosure of, e.g., the WO 99/04265 document and combine them. Rather, for anticipation to exist, the document(s) must clearly and unequivocally disclose all of the elements of Applicants' claimed subject matter *with sufficient specificity*. Applicants' claims are not disclosed with sufficient specificity in WO 99/04265, or in any of the other cited documents, to constitute anticipation of Applicants' claimed subject matter.

Applicants respectfully direct the Examiner's attention to the Board of Patent Appeals and Interferences' decision in *Ex parte* Bobsein et al., (Appeal No. 2005-1332), and to *In re Arkley*, 172 U.S.P.Q. 524 (CCPA 1972), which is cited in *Ex parte* Bobsein, copies of both of which are attached. Those decisions stand for the proposition that, for anticipation to stand, there must not be picking and choosing among possible combinations. Applicants respectfully submit that in the rejections, the Office has improperly picked and chosen from among possible combinations, to arrive at the claimed invention. Applicants submit that the rejection improperly utilizes Applicants' disclosure as a guide to pick and choose from the broad disclosure of WO 99/04265, in an attempt to arrive at Applicants' claimed subject matter. This is not permissible, and for at least this reason, the rejection should be withdrawn.

Applicants further submit that SCANLAN, SCANLAN-II, NAKATSURA, ISHIHARA, HORNE, KASER, or COCKS do not teach a cancer vaccine, much less a cancer vaccine as claimed herein. For example, Applicants submit that neither SCANLAN, SCANLAN-II, NAKATSURA, ISHIHARA, HORNE, KASER, nor COCKS teach or fairly suggest a cancer vaccine which comprises the disclosed and claimed DNA and which further comprises an adjuvant.

Thus, because none of the references cited by the Examiner teach a cancer vaccine as disclosed and claimed herein, Applicants submit that the disclosed and claimed subject matter is not anticipated or fairly suggested. Applicants therefore respectfully request withdrawal of the rejections under 35 U.S.C. § 102(b) and (e).



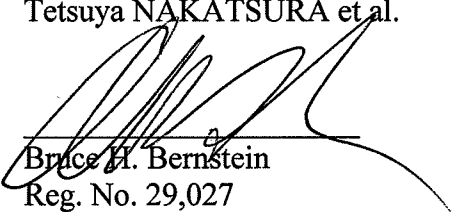
**CONCLUSION**

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow all the pending claims.

No additional fee is believed due at this time. If, however, any additional fee is necessary to ensure consideration of the submitted materials, the Patent and Trademark Office is hereby authorized to charge the same to Deposit Account No. 19-0089.

Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully submitted,  
Tetsuya NAKATSURA et al.



Bruce H. Bernstein  
Reg. No. 29,027

May 5, 2008  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191

Arnold Turk  
Reg. No. 33094